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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,636	10/19/2001	Sidney T. Smith	FLM-5169	8615
7590 05/05/2004			EXAMINER	
MARK J. BUONAIUTO, ESQ. BAXTER INTERNATIONAL INC. LAW DEPARTMENT ONE BAXTER PARKWAY, DF2-2E			BISSETT, MELANIE D	
			ART UNIT	PAPER NUMBER
			1711	
DEERFIELD,			DATE MAILED: 05/05/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
•	10/044,636	SMITH ET AL.				
Office Action Summary	Examiner	Art Unit				
	Melanie D. Bissett	1711				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address						
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPL' THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a repl' - If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be tin y within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 15 M	larch 2004.	•				
	s action is non-final.	*				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under I	Ex parte Quayle, 1935 C.D. 11, 4	53 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>1-20,22,23,25,26,28,39-45 and 61-6</u>	7 is/are pending in the application					
4a) Of the above claim(s) is/are withdra						
5) Claim(s) is/are allowed.						
6) Claim(s) 1-20,22,23,25,26,28,39-45 and 61-6	<u>7</u> is/are rejected.					
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/o	or election requirement.					
Application Papers						
9) The specification is objected to by the Examine	er.					
10)⊠ The drawing(s) filed on <u>15 August 2003</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correct	ction is required if the drawing(s) is ob-	pjected to. See 37 CFR 1.121(d).				
11)☐ The oath or declaration is objected to by the E	xaminer. Note the attached Office	e Action or form PTO-152.				
Priority under 35 U.S.C. § 119	4					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documen	ts have been received.					
2. Certified copies of the priority documen		tion No				
3. Copies of the certified copies of the price	ority documents have been receiv	red in this National Stage				
application from the International Burea						
* See the attached detailed Office action for a list of the certified copies not received.						
* 9						
Attachment(s) 4) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail [Date				
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08	· =	Patent Application (PTO-152)				
Paper No(s)/Mail Date	6) U Other:					

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1. The rejections based on 35 USC 102 and 103 have been withdrawn based on the applicant's amendments and arguments. However, the new matter rejection for the added melting point limitation has been maintained. Also, a rejection based on 35 USC 112, 2nd paragraph has been added.

2. The request filed on 3/15/04 for Continued Examination under 37 CFR 1.114 based on parent Application No. 10/044,636 is acceptable and an RCE has been established. An action on the RCE follows.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 4. Claims 1-17, 19, 39-45, and 61-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
- 5. From a prior Office action:

[T]he claims recite "having a DSC melting point of 100°C or lower". The specification gives no guidance to such a limitation. Although the applicant points to the specification's mention of Affinity or Exact polymers as suggestion for the limitation, no specific Affinity or Exact polymers are mentioned. One of ordinary skill in the art would not be guided by the specification to choose a polymer fitting such a limitation. Note that, although many of the polymers in the Affinity and Exact families have melting points lower than 100 °C, others do not (see data sheets for Affinity PL 1840 and Affinity PT 1409). Thus, the vague mention of Affinity or Exact polymers in the specification does not lead one to the limitation of a melting point lower than 100 °C.

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- 6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 7. Claims 1-20, 22-23, 25-26, 28, and 61-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 8. Regarding claims 1 and 18, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

- 9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 10. Claims 1, 4-7, 9-14, 16-17, 39-45, and 61-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith et al. (US 6,362,843) can be found on the applicant's Form PTO-1449.
- 11. The applied reference has a common inventor with the instant application.

 Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

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the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

- 12. Smith teaches a multiple layer structure having solution contact and outer exterior layers, where the outer layers are chosen from polyamides, polyesters, and polyolefins (abstract). The modulus of the overall film is less than 50,000 psi (col. 3 lines 18-28). Polyamide materials include ring-opening products nylon 6, nylon 10, or nylon 12, while condensation products nylon 66, nylon 6,10, and dimmer fatty acid polyamides are also included (col. 4 lines 1-14). Single-site catalyzed polyolefins are used, where ethylene-butene copolymers are preferred (col. 4 lines 57-67). Affinity and Exact materials are used, and the copolymers should have densities of 0.880-0.910 g/cc (col. 5 lines 1-3). Tie layers include blends of modified and unmodified polyolefins, where maleic anhydride is a preferred modifying agent (col. 5 lines 4-47). The thicknesses of the layers read on the applicant's claimed ranges (col. 5 line 66-col. 6 line 10).
- 13. Regarding slip agents, the reference does not require the use of such slip agents; thus, it is the examiner's position that the reference teaches structures essentially free of slip agents. The layers are coextruded and formed into medical containers (col. 6 lines 38-60).
- 14. Regarding the DSC melting point of the materials, note that Affinity PL1880 is exemplified. This material has been shown by the applicant to have a melting point of 100 °C.

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- 15. Regarding the burst pressure of the films, it is noted that the prior art films are made of the same materials and thicknesses as employed by the applicant. Thus, it is the examiner's position that the structures would inherently possess the applicant's claimed burst pressure values.
- 16. Claims 1, 4-7, 9-10, 14, 16-17, 39-41, and 61-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Ramesh et al. '392.
- 17. Ramesh discloses multi-layered films comprising a polyolefin outer layer and an outer layer selected from polyester, polyamide, and polyurethane (abstract). The polyolefin layer comprises a single-site catalyzed homogeneous ethylene/α-olefin polymer having a preferred melting point below 100 °C and a preferred carbon content of 4-8 carbons in the α-olefin (col. 11-col. 12 line 3). The polyolefin also preferably has a density of less than 0.898 g/cc to create a layer of up to 4-mil thickness (col. 15 lines 28-58; col. 16 lines 22-23). Materials for the other outer include the applicant's claimed nylon materials at a thickness of up to 4 mils (col. 19 lines 22-28, 49-50). Tie layers are included at a thickness of 0.13 or 0.16 mils (col. 20 lines 16-20; example 1). The overall films have modulus values as low as 40,000 psi (col. 20 lines 42-50).
- 18. Regarding slip agents, the reference does not require the use of such slip agents; thus, it is the examiner's position that the reference teaches structures essentially free of slip agents. The layers are coextruded and formed into packaging containers (col. 1 lines 7-11; examples).

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19. Regarding the burst pressure of the films, it is noted that the prior art films are made of the same materials and thicknesses as employed by the applicant. Thus, it is the examiner's position that the structures would inherently possess the applicant's claimed burst pressure values.

Claim Rejections - 35 USC § 103

- 20. Claims 11-13 and 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramesh et al. in view of Adur et al.
- 21. Ramesh applies as above, teaching the use of tie layers but failing to specify a blend of a modified polyethylene copolymer with a polyolefin polymer. Adur teaches adhesive blends of grafted polyethylene homopolymers or copolymers, LDPE or LLDPE, and a poly(α-olefin), where the blends have improved adhesive strength with both polyolefins and polar substrates (col. 1 lines 36-56; col. 2 lines 4-10). The adhesives can be applied to substrates and co-extruded to form a number of articles (col. 1 lines 57-68). Examples of specific composites are listed, including polyolefin/adhesive/nylon, polyolefin/adhesive/EVOH, and polyolefin/adhesive/polyester (col. 4 lines 15-27). Maleic anhydride is noted as a preferred modifying monomer (col. 2 lines 49-65; examples 40-41, at least). Therefore, it is the examiner's position that it would have been prima facie obvious to use the adhesive blend of Adur's teaching in the composite of Ramesh's invention to improve the adhesive strength between the polyolefin and polar substrate.

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22. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being obvious over Smith et al. in view of Mueller.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

23. Smith applies as above, teaching specific polyamides and also teaching copolyesters for use as outer layers but failing to note the use of the applicant's claimed polyester ethers. Mueller teaches multilayer films for flexible container purposes, where Ecdel materials are taught as equivalent to nylon 66, nylon 6,10, and nylon 12 as

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materials providing improved heat resistance and abuse resistance (col. 9 lines 37-53). Ecdel materials are noted by the applicant as PCCE polymers. It is the examiner's position that it would have been prima facie obvious to use PCCE polymers as outer layers in Smith's invention to provide multilayer films having equally improved heat resistance and abrasion resistance.

- 24. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramesh et al. '392 in view of Mueller.
- 25. Ramesh applies as above, teaching specific polyamides and also teaching polyesters for use as outer layers but failing to note the use of the applicant's claimed polyester ethers. Mueller teaches multilayer films for flexible container purposes, where Ecdel materials are taught as equivalent to nylon 66, nylon 6,10, and nylon 12 as materials providing improved heat resistance and abuse resistance (col. 9 lines 37-53). Ecdel materials are noted by the applicant as PCCE polymers. It is the examiner's position that it would have been prima facie obvious to use PCCE polymers as outer layers in Ramesh's invention to provide multilayer films having equally improved heat resistance and abrasion resistance.

Allowable Subject Matter

26. Claims 18, 20, 22-23, 25-26, and 28 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

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27. The following is a statement of reasons for the indication of allowable subject matter:

28. The closest prior art, Smith et al., teaches multilayer structures having outer layers of polyolefins and polyesters or polyamides. However, the reference does not teach bonding the polyolefin layer directly to the polyester or polyamide layer. Furthermore, the removal of any intermediate layers would destroy the invention of the reference. Thus, it is the examiner's position that the applicant's multilayer structure of claim 18 is novel and unobvious over the prior art.

Response to Arguments

29. In response to the applicant's argument that the specification, in citing Affinity and Exact materials, provides support for the limitation "having a DSC melting point of 100 °C or lower", the examiner respectfully disagrees. One skilled in the art, considering the original specification, would not recognize the melting points of the outer layers as a feature of the invention. The melting points are not noted in the specification and are especially not noted as a feature which is important to the inventive concept. Thus, one would not be guided by the specification to specifically choose materials having a certain melting point. The examiner has pointed to the fact that Affinity and Exact polymers are not limited to have the claimed melting points (some have values outside the claimed range). Also, note that the claims are not limited to specific Affinity or Exact polymers but to all ethylene/α-olefin copolymers having certain properties. The specification certainly does not provide support for polymers other than Affinity or Exact

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having certain melting points. For these reasons, it is the examiner's position that the specification does not provide support for the limitation "having a DSC melting point of 100 °C or lower".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie D. Bissett whose telephone number is (571) 272-1068. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mdb

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